

**COPY OF UNITED STATES PATENT  
APPLICATION  
SERIAL NO. 10/271,344  
FILED OCTOBER 15, 2002  
NOW US 6,969,217**



Atty. Docket No.: 9494.17965-PROV FOR

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Patent

#### ENDOVASCULAR ANEURYSM REPAIR SYSTEM

##### Related Application

This application claims the benefit of co-pending United States provisional application Serial No. 5 60/333,937 filed 28 November 2001.

##### Background of the Invention

The invention relates generally to the attachment of a vascular prosthesis to a native vessel, and in particular, to a method and system of devices for 10 the repair of diseased and/or damaged sections of a vessel.

Description of Related Art. The weakening of a vessel wall from damaged or diseased can lead to vessel dilatation and the formation of an aneurysm. Left 15 untreated, an aneurysm can grow in size and will eventually rupture.

For example, aneurysms of the aorta primarily occur in abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. 20 Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or 25 damaged section of vessel can eliminate the risk of

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vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight or bifurcated configuration, is installed and then permanently attached  
5 and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate  
10 changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co morbidities.

15 Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are  
20 delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical  
25 aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the  
30 same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need for an endovascular aneurysm repair system that first provides a  
35 prosthetic graft, which can adapt to changes in aneurysm

morphology and be deployed without damaging the native vessel and second, a separate endovascular fastening system that provides permanent graft attachment to the vessel wall.

5     Summary of the Invention

The methods and apparatus for implanting radially expandable prostheses in the body lumens are described. In particular, the present invention provides improved methods and systems for implanting vascular 10 stents and stent-grafts into blood vessels, including both arterial and venous systems. In the exemplary embodiments, stent-grafts are placed in vasculature to reinforce aneurysms, particularly abdominal aortic aneurysms.

15       In the first aspect of the present invention, a radially expandable prosthesis is placed in a body lumen by first expanding at least one scaffold of the prosthesis at or near an implantation site within the body lumen, e.g., at or from vasculature on one side of 20 an aneurysm. After expanding the scaffold of the prosthesis, a plurality of fasteners are introduced through the prosthesis in the region in the scaffold to anchor the scaffold in place. The scaffold may be elastic, typically comprised of a shape memory alloy 25 elastic stainless steel, or the like. For elastic scaffolds, expanding typically comprises releasing the scaffolding from constraint to permit the scaffold to self-expand at the implantation site. The constraint may be radial constraint, i.e., placement of a tubular catheter, delivery sheath, or the like over the scaffold 30 in order to maintain the scaffold in a radially reduced configuration. Expansion is then achieved by pulling back on the catheter sheath to permit the scaffold to return to its larger diameter configuration. 35 Alternatively, the scaffold may be constrained in an

axially elongated configuration, e.g., by attaching either end of the scaffold to an internal tube, rod, catheter or the like, to maintain the scaffold in the elongated, reduced diameter configuration. The scaffold 5 may then be released from such axial constraint in order to permit self-expansion.

Alternatively, the scaffold may be formed from a malleable material, such as malleable stainless steel or other metals. Expansion may then comprise applying a 10 radially expansive force within the scaffold to cause expansion, e.g., inflating a scaffold delivery catheter within the side of the scaffolding order to affect the expansion.

The vascular prosthesis may have a wide 15 variety of conventional configurations. In the preferred placement of the vascular stent-graft, prosthesis would typically comprise a fabric other blood semi-impermeable flexible barrier which is supported by a scaffold, typically in the form of a stent. A stent can have any 20 conventional stent configurations, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent structure may extend the entire length of the graft, and in some instances will be longer than the fabric components of the graft. Alternatively, the stent 25 will cover only a small portion of the prosthesis, e.g., being present on at 1,2, or 3 ends. The stent may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms when the stent graft extends 30 into the iliac arteries. In certain instances, the stents may be spaced apart along the entire length, or at least a major portion of the entire length, of the stent-graft, where individual stent structures are not connected to each other directly, but rather connected to the fabric 35 or other flexible component of the graft.

Introduction of the fasteners will typically be effected after the prosthesis has been initially placed. That is initial placement will be achieved by self-expansion or balloon expansion, after which the 5 prosthesis is secured or anchored in place by the introduction of a plurality of individual fasteners, preferably helical fasteners which are rotated and "screwed into" the prosthesis and vessel wall. Fasteners may be placed through the fabric only, i.e., avoiding the scaffold structure. Alternately, the fasteners can be introduced into and through portions of the scaffold 10 structure, optionally through receptacles or apertures which have been specially configured to receive the fasteners. In some cases, of course, fasteners will be 15 introduced both through the fabric and through of over the scaffold structure.

In the exemplary embodiment, the fasteners are helical fasteners, which are introduced singly, i.e., one at a time, in a circumferentially spaced-apart pattern 20 over an interior wall of the prosthesis. Usually, the fasteners will be introduced using a fastener applier which carries a single fastener. Fastener applicers which carry a single fastener can have a lower profile and may be more effective and less traumatic than fastener 25 applicers which carry multiple fasteners. The present invention, however, does contemplate that in certain embodiments the fastener applier may carry multiple fasteners. Moreover, the fastener applier may simultaneously deploy multiple fasteners in the preferred 30 circumferentially spaced-apart space pattern described above. Usually, from 2-12 fasteners will be applied at each end of the prosthesis to be anchored. The 2-12 fasteners will usually be applied in a single circumferentially space-apart row that may be applied in 35 more than one row with individual fasteners being axially

aligned or circumferentially staggered. In a preferred embodiment, the intraluminal fastener applier of the present invention comprises a guide component and an applier component. The guide component, for example, 5 comprises a tubular body having a deflectable distal tip and, optionally, a stabilizer for holding the deflected tip against a location in the graft to which the fastener is to be applied. The applier component is insertable through a lumen of the guide component and carries at 10 least a single helical or other fastener. A rotation driver is provided for rotating and advancing the helical fastener so that it penetrates the graft and underlying vessel wall to anchor the graft firmly in place.

Brief Description of the Drawings

15 The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings, wherein:

20 Fig. 1 is a perspective view of one embodiment of an endovascular graft delivery device shown positioned within an abdominal aortic aneurysm;

Fig. 2 is a perspective view of one embodiment the deployment of an endovascular graft within the aneurysm of Fig. 1;

25 Fig. 3 is a perspective view of a fully deployed straight endovascular graft of Fig. 2;

Fig. 4 is a perspective view of a fully deployed bifurcated endovascular graft broken away to show an anchoring scaffold at one end;

30 Fig. 5 is a perspective view similar to Fig. 5 showing an alternative scaffold structure;

Fig. 6 is a perspective view showing one embodiment of a device for directing the fastener applier;

35 Fig. 7 is a perspective view showing the

device of Fig. 6 upon insertion within the deployed endovascular graft of Fig. 3 with both the graft and scaffolding broken away;

5 Fig. 8 is a perspective view of the device of Fig. 6 showing activation of one embodiment of a stabilizing device attached to the directing device;

Fig. 9 is a perspective view of the control assembly in Fig. 8 articulating the directing device of Fig. 6;

10 Fig. 10 is a perspective view of an alternative embodiment of the stabilization device of Fig. 8;

15 Fig. 11 is a perspective view showing the activation of the alternative stabilization device of Fig. 10;

Fig. 12 is a perspective view showing another embodiment of the stabilization device of Fig. 8;

Fig. 13 is a perspective view showing activation of the stabilization device of Fig. 12;

20 Fig. 14 is one embodiment of the fastener applier;

Fig. 15 is a perspective view of the fastener applier of Fig. 14 being positioned within directing device of Fig. 6;

25 Fig. 16 is an enlarged cross-sectional view of one embodiment of the fastener applier of Fig. 14;

Fig. 17 is an enlarged cross-sectional view of the attachment applier showing one embodiment of the proximal end of the helical fastener and the drive mechanism;

Fig. 18 is an enlarged perspective view of one embodiment of the helical fastener of Fig. 16;

30 Fig. 19 is an enlarged view of the attachment applier showing one embodiment of the control assembly that activates the fastener applier;

Fig. 20 is an enlarged view of the attachment applied activated with a fastener implanted into the graft and vessel wall;

5 Fig. 21 is an enlarged view of the completed attachment of the proximal graft of Fig. 3 to the vessel wall with fasteners;

Fig. 22 is a perspective view of the graft of Fig. 4 completely attached to the vessel.

Detailed Description of the Invention

10 Fig. 1 depicts an endovascular graft delivery catheter 10 being positioned within an abdominal aortic aneurysm 11 over a guidewire 12. Fig. 2 depicts the initial stage of graft deployment within a vessel. The delivery catheter 10 has a movable cover 13 over the  
15 graft. When the cover is pulled proximally the graft 14 expands to contact the internal walls of the vessel. It is contemplated that the graft could be self-expanding or utilize an expanding member such as a balloon or mechanical expander. The process of graft deployment is  
20 continued until the graft is fully deployed within the vessel. It is contemplated that the graft could be in either a straight or bifurcated form. Fig. 3 depicts a completely deployed straight graft 14 and Fig. 4 depicts a completely deployed bifurcated graft 15. The guidewire  
25 11 used to deliver and position the graft remains within the vessel for access of the fastener attachment system. One embodiment of the graft scaffolding 16 (stent) is illustrated in the area broke away in Fig. 4. The stent is in the form of a simple zigzag pattern, however it is  
30 contemplated that the stent design could involve more complex patterns 17 as depicted in Fig. 5. Although only one stent structure within the graft is depicted, in Fig. 4 and 5, it is contemplated that multiple independent stent structures could be incorporated into the graft.  
35 1391 Fig. 6 depicts one embodiment of the directing

device 18 with an obturator 19 positioned within the lumen of the directing device and extending past the distal of the tip of the directing device. The obturator has a lumen to allow for delivery over a guidewire. Fig. 5 7 depicts the directing device being positioned within the deployed endovascular graft over a Quidewire 12. The directing device has an incorporated stabilizing device 20 to aid in maintaining position of the directing device within the vessel. In one embodiment, the stabilizing device 20 is spring-loaded and is positioned for use when the obturator in the directing device is removed Fig. 8. The directing device is activated though a control assembly 21 as seen in Fig. 8. In one embodiment the control assembly 21 features a movable wheel or lever 22, 10 which deflects the distal tip 23 of the directing device 18 to the desired location as seen in Fig. 9. It is contemplated that the control assembly for the directing device could be activated mechanically, electrically, hydraulically or pneumatically. The control assembly has 15 a through lumen to allow for the passage of the obturator and fastener applier. Fig. 10 depicts another embodiment the stabilizing device as a movable strut assembly 24. The movable strut assembly is activated through a lever 20 on the control assembly Fig. 11. In both embodiments 25 (Fig. 7 and 10) the stabilizing device is distal to the end of the directing device. In another embodiment the stabilizing device could be in the form of an expandable member 26 adjacent to the distal tip of the directing device Fig. 12. In one embodiment, the expandable member 30 26 is shown activated through a lever 25 on the control assembly Fig. 13. However it also contemplated that this type of stabilizing device could also be inflatable. In all embodiments the stabilizing device could be use to stabilize the directing member either concentrically or 35 eccentrically within the vessel.

In another embodiment of the invention a separate tubular device could be used in cooperation with the directing device and to access the vessel. This separate tubular device could incorporate the stabilizing devices used above with the directing device.

Fig. 14 depicts one embodiment of the fastener applier 27. Fig. 14A is a detail view of the distal end of the fastener applier. Fig. 15 depicts the fastener applier being positioned through the lumen of the directing device to the site where a fastener will be installed.

Fig. 16 is an enlarged cross-sectional view of fastener applier 27 and directing device 18. In one embodiment of the fastener applier the helical fastener 28 is rotated via a fastener driver 29 through a drive shaft 30 that is connected to the control assembly 31. The drive shaft 30 can be made of any material that allows for both bending and rotation. The drive shaft is connected to the fastener driver 29, which engages and imparts torque to the helical fastener. Fig. 16 illustrates the coils of the helical fastener 28 engaged with internal grooves 32 within the fastener applier. It is contemplated that the grooves could be positioned along the entire length of the fastener or within a portion of its length. Fig. 17 is an enlarged cross-sectional view of the fastener applier 27 with a cross-section of the fastener driver 29 depicting one embodiment of engagement between the fastener driver and helical fastener 28. In this embodiment the proximal coil of the helical fastener is formed to produce a diagonal member 33, which crosses the diameter of the helical fastener. Similar helical fasteners are described in U.S. Patent No. 5,964,772; 5,824,008; 5,582,616; and 6,296,656, the full disclosures of which are incorporated herein by reference.

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Fig. 18 depicts one embodiment of the helical fastener 28 showing the diagonal member 33. Fig. 19 depicts one embodiment of the fastener applier 27 during activation of the fastener applier control assembly.

5 Activation of the control assembly rotates the drive shaft, faster driver and helical fastener. This rotation causes the helical fastener 28 to travel within the internal grooves 32 of the fastener applier and into the graft 14 and vessel wall 34 Fig. 20. It is contemplated that the control assembly for the fastener applier could

10 be activated mechanically, electrically, hydraulically or pneumatically.

Fig. 21 illustrates a completed helical fastener 28 attachment of the graft 14 to the vessel wall 34. It is contemplated that one or more fasteners will be required to provide secure attachment of the graft to the vessel wall.

Fig. 22 illustrates a perspective view of a graft prosthesis attached to the vessel wall both proximally and distally. It is contemplated that the present invention can be used for graft attachment of both straight and bifurcated grafts 15 within the aorta and other branch vessels.

It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the directing device, fastener applier and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic

device within the vascular system and generally within the body.

The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.